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I. Muka / A. Huba

Design of a Special Biomechanic Actuator

ABSTRACT

This paper presents the current investigation in cooperation of the Dept. of Mechatronics, Optics and Informatics in Mechanical Engineering and the Surgical Clinic Nr. I. of the Semmelweis University since 1998. The goal of this activity namely is to find an optimal technical solution for urinary and rectal artificial sphincter creating a suitable shape for the sphincter actuator system which simulates the natural behavior of the closing muscles. We use the Ansys FEM simulation for the optimal actuator shape. The results show that the closing process could be modeled well.

1. INTRODUCTION

The inability for retention of urine or stool makes the normal life of the patients impossible and heavy. The muscle function can be reconstructed in several cases. One of these methods is if stimulating material will be introduced into the closing muscles. Another possibility is to stimulate the muscles with continuous electric signal. In further cases, there is a possibility to replace of the inactive muscles with parts of own skeletal musculature of the patient. There are some cases wherein for people suffering from these illnesses only the implantation of artificial sphincter may bring solution for their problem [1]. The implantation will indicated if the normal function of the muscles can not be restored. The sizes of these instruments are passed to the person to ensure the success of implantation.

1972 the first artificial urinary sphincter was implanted successfully and the result of this encouraged the scientists to create artificial sphincter also for the rectal tract to help in case of incontinence.

The first experiences and results with special anal closing rings support the hope for

solving also this heavy problem.

However information and results of long time investigations are not available yet numerous papers shows that this way of solution is simple, effective and safe and advantageous for the sick people bringing hope for a better life quality.

During the past time the investigators suggested and patented unbelievable number of solutions for constructions stopping incontinence. Some of them have been realised and implanted, but neither turned out to be a flawless solution, because the usage of them did not spread up to the present days. There are some solutions that works by mechanical principle, but most of them work as inflatable cuffs and have a ring shape fitted around the colon. By use of these implants significant improvement of the life of many patients could be achieved however we can not give up to find an optimal solving of the problem. It is important to know that even in case of successful implantation only 5 years of perfect function can be guaranteed so the problem of incontinence can not be solved yet for the whole life.

Studying and analysing the reports about the implantations our Department try to find a better solution by optimisation of shape of the closing apparatus which in most of case are responsible for the cuff dysfunction.

2. DEVELOPING A NEW CLOSING SYSTEM

We started the development with the investigation of the contemporary used systems. In the next subchapter, we briefly present the most frequently used closure system, and its problems.

2.1 Analysis of existing constructions

During the last twenty years several solutions have been developed for the substitution of the disable closing muscles. Some of these have been approved also in the praxis. Some of these ideas could be held completely or partially irrealistic. Without criticising of the constructions we show some characteristic examples based on the researche among the USA patents.

The working principle of one version [2] of them bases on a simple principle . According the idea of the investigator the device should be placed by operation into the body. The closing will be carried out by the turning of the ends of the sticks fitted

in the lover ring. The diameter of the middle section of the device decreases as result of the turning see Fig. 1.

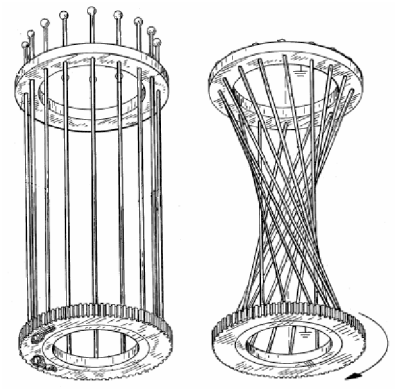

Fig. 1.
Closing device with sticks

Among the closing systems there is a solution consisting of three active chambers partially using high elastic material for the construction [3]. The first chamber is fitted inside the rectum the second one inside of the rectal musculature and the third one outside of the body intragluteal (between the buttocks, see Fig. 2.). Setting the device under inner pressure the first end the third chambers serves only for the positioning. The second chamber closes the rectum by expansion due to the inner pressure.

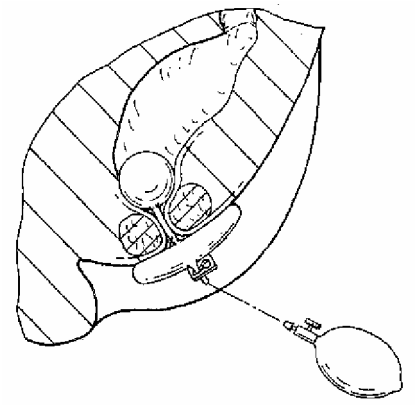

Fig. 2.
Three-chamber closing system

The next closing system described below intents to achieve the continence using ring shaped cuff situated in the middle section of the device [4]. The cuff and the other operation elements (Fig. 3.) will be placed by operation into the body. The cuff is a

hollow chamber around the colon which can operate by the patient. The cuff produces the necessary minimum pressure on the wall of the colon to produce the closing without destruction of the tissues.

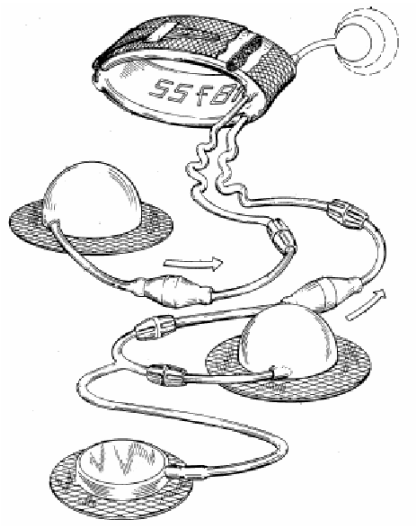

Fig. 3.

Three-balloon closing system

The device consists of two thin pipeline systems for the liquid flow each of them having separate storage balloons and control valves. These two storage balloons are connected with separate pipelines to the cuff. Each of the balloons can operate separately to ensure the controlled pressure for the closing. The aim is to produce the continence using possible minimal pressure. The reserve balloons must be placed in well-considered area easy to achieve by the patient. The selective operation of both balloons ensures different pressures for the closing.

As far as for a patient with incontinence only the implantation of an artificial sphincter can solve the problem in numerous cases the products of the firm AMS are used. The device [5] consists of three units made from silicone elastomer (see Fig. 4.):

1) Cuff
2) Reservoir and pressure regulator
3) Controlling pump

There are cuffs with different length 2 – 2,5 [cm] and width 9 – 14 [cm] on the market. The reservoir and pressure regulator produces the inner pressure of 60 – 90 [cm] water-column millimeters.

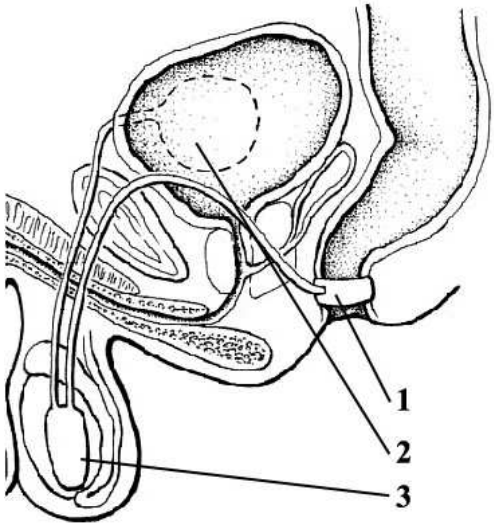

Fig. 4.
Implanted artificial sphincter

The control pump is a special shaped unit which can be activated manually. The cuff fixed by stitching around the colon is connected with a silicone rubber pipeline to the control pump. The pump is placed in case of men in the scrotum and in the labia at women and connected further to the reservoir placed on a Retzius' space. The system is filled by physiological solution until optimum level. Activating the device the liquid flow blows up the cuff which closes the colon ensuring continence. The pressure inside of the cuff is ensured by the reservoir. Having a need the patient presses the pump any times and this let flow the liquid from the cuff into the reservoir. Now the cuff empties and the colon will be free for stool. The regulator lets the flow of liquid back to the cuff slowly in 7-10 minutes to close the colon again. If there is a need for a longer process it is enough to press the pump again or to stop the system with a special button. This press less function is used also during the after implantation stage.

2.1.1 Problems, complications

The implanted artificial sphincter caused in some cases complications which indicated the change of the implant or in worst case the final remove of it. The most frequent complications are in connection with infections mainly in area of the cuff.
Further complications reported are the "wandering" of the cuff, erosion of the colon, heavy stool, pain and sepsis [6].
If the inner pressure in the cuff is too high necrosis of the colon can be caused.

Investigations for the reasons the cuff dysfunctions have been made before at the Department. L. Molnár [7] showed in his PhD dissertation that the mechanical instability of the inner surface of a torus shaped cuff causes folds. The Fig. 5. shows the simulation model of a torus-shaped cuff in the phase of mechanical instability caused by the inner pressure.

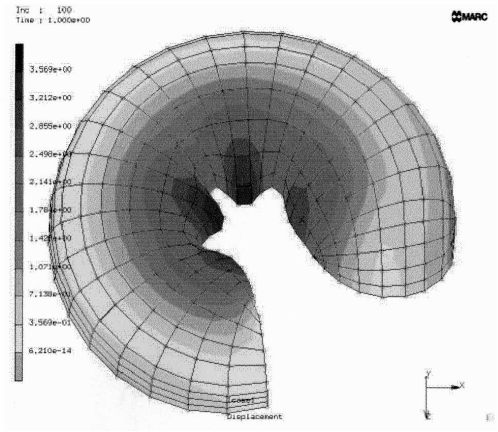

Fig. 5.
Simulation of the torus shaped cuff [7]

This folds or shrivels pinch the fine intestinal wall causing the above mentioned complications.

2.2 The new developed closing system

To eliminate the complications showed in the previous chapter we started an investigation for the development of an artificial sphincter system based on a new principle which simulates the natural function of the closing muscles.

2.2.1 Demands for the structure of closing system

During the layout process numerous conditions often standing in contradiction are to be taken into consideration.

The closing system must not limit the normal function of the neighbouring organs and the blood circulation in the intestinal wall. It has to be small as possible. The opening cross section of the colon can be small in case of liquid secret but in normal situation the system must not hold up or block the passing. Special medicaments may shift the state of secret but in each case the demand for outer diameter of the closing system

has to be minimum 40 mm. The transparency for gas can be guaranteed by the small slits induced by the closing in form of bending colon sections. The outer ring of the closing system has to be placed and fixed to the muscles around the colon. To be able to hold the closing cuff in the implanted position the system has to have suitable length. The closing function works at 30 mm length. The outer ring also supports and fits the hydraulic actuators formed as special balloons inside which must not shift to each other during the normal operations. The shape of this actuator balloons has to ensure that the colon and the neighbouring tissue won't be pinched under any conditions. In the basic pressure state the actuators have to ensure the complete closing since to hold this system under the overpressure is inconvenient. Normally the colon will be closed by the contraction of different groups of closing muscles. The main task of the simulations during the development was to create an artificial system using high flexible structures like special formed balloons comparable to the original.

2.2.2 The material of balloons

We use silicone rubber as construction material. The medical silicon is ideal for implants since the evaluation process can be reduced if one type of this certificated material is applied. More about the special properties of medical rubber is to read in [8].

The mechanical properties of silicone rubbers differ however significant form other construction materials. This polymer is characterised by high elastic shape changing since their elongation may surpass 400 % but the compression of this material is really difficult. Further problem means the non linear dynamic behaviour like relaxation and creep which are to be taken into consideration during the layout of systems made from silicone rubber. It is important for example to know constructing the balloons that the material ought to be bended or stretched instead of direct compression.

2.2.3 First variant

The first variant consists of two balloons placed on the opposite side of the colon which close this if the inner pressure increases.

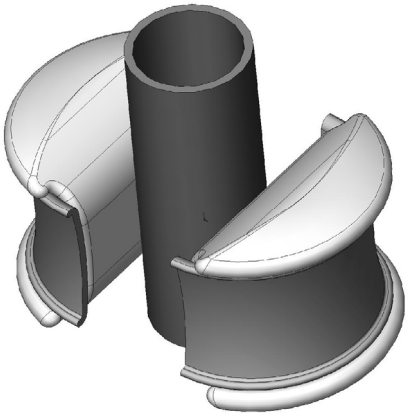

Fig. 6.
Positioning of balloons for closing

The colon was modelled as a thin wall pipe. The balloons open the passage by drawing down of the liquid. Both balloons are fixed on a fibre reinforced cuff which encircles the system (Fig. 6.). The cuff fitted to the neighbouring muscle tissues ensures support for the balloons to change their form under inner pressure versus colon. The modelling was done by use of the Ansys FEM program. The shape of the balloon is shown in the Fig. 7.

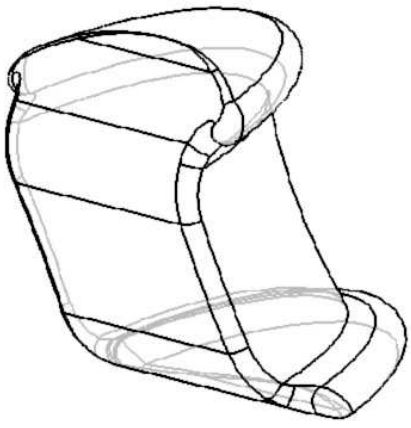

Fig. 7.
The balloon closing actuator

CAD drawings of this actuator in different forms were analysed by Ansys. The results of simulations showed that the closing could be realised perfectly under inner pressure at opening however folds and crumples appear on the inner surface of the balloons decreasing the pressure. This could be extremely dangerous since the free passage will be hindered the thin intestinal wall of the colon can be injured and the balloons get damaged (Fig. 8.). Fig. 8. shows the shape changing in some critical areas of the balloon following the drawing down.

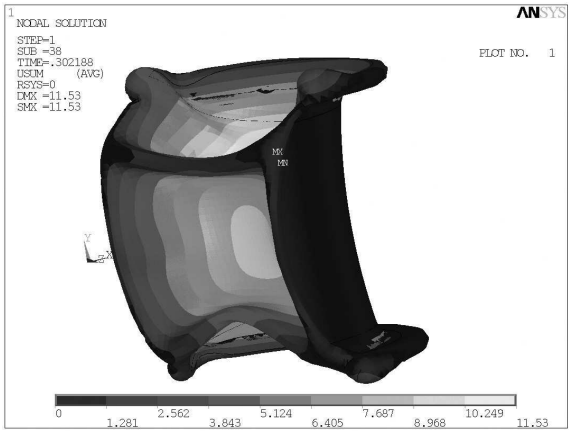

Fig. 8.

Shape changing of the balloon following draw down

To eliminate this problem further different balloon shapes were analysed by FEM. The result of the optimisation process is shown in the Fig. 9.

2.2.4 New variant

Better taking the material properties of silicone rubber into consideration and based on the results of the first variant the second version was constructed. See the form in the Fig. 9.

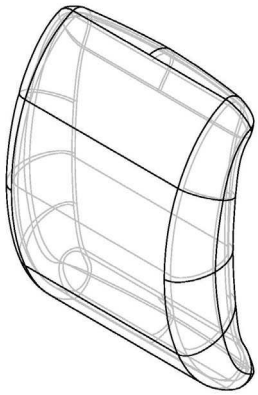

Fig. 9.

The modified shape

The FEM simulations showed that this geometry and shape results more suitable deformation drawing dawn the liquid from the balloon see Fig. 10.

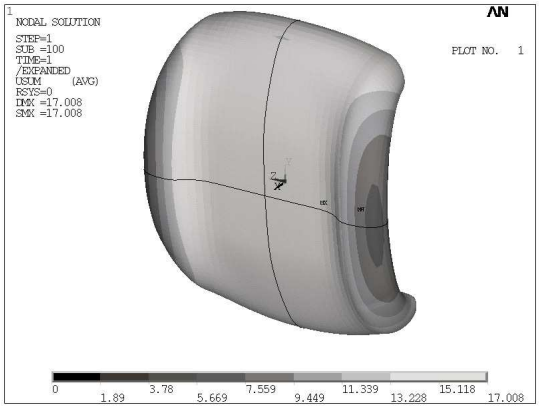

Fig. 10.

Shape changing of the new variant during drawing down

The figure shows no folds occurred in the first version so we proved the closing process by simulations. There were the parameters of the colon also needed which have been determined by strain-stress tests of “in vitro” probes. The start position of the simulation is shown in the Fig. 11.

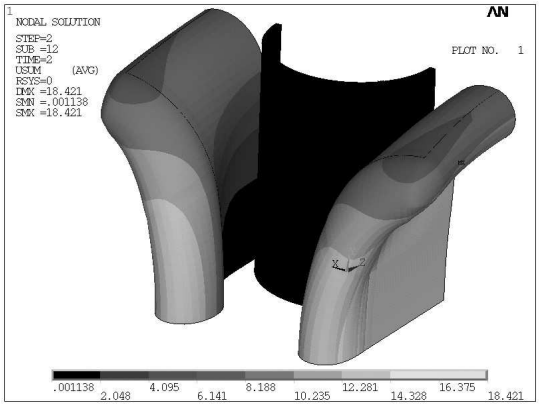

Fig. 11.

The balloons and the colon in opened passage

The results of the simulations show that the closing process is suitable since no one of the former problems could be detected see Fig. 12.

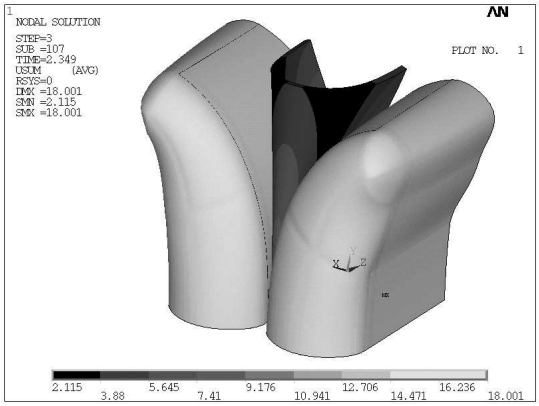

Fig. 12.

The balloons and the colon in closed situation

The shape of the balloons allows not only the perfect closing and the good passage but their upper section ensures the collecting of secret in a cornet-shaped form of colon. The balloons support softly the intestinal wall decreasing the load of this.

3. CONCLUSION

The just finished simulations showed that there is a way to eliminate the problems of the folds on the inner surface of the closing balloons. Even the cuff form may cause complications pinching the intestinal tissues. Our investigation shows that a special

shaped balloon approximates better the natural closing of colon with muscles than the recently used cuff systems. The investigation goes on.

Acknowledgements

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